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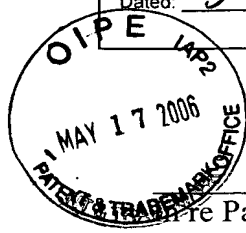
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EL 995017856 US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 5-17-06

Signature:

[Signature]
(Juan Quintero)

Docket No.: 30754/39959
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of:

David E. Clarke

Application No.: 10/823,906

Confirmation No.: 6103

Filed: April 14, 2004

Art Unit: 1614

For: MATERIALS AND METHODS FOR THE
TREATMENT OF ULCERATIVE COLITIS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A summary/abstract translation of the non-English language references is enclosed.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

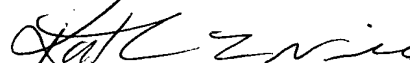
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 30754/39959. A duplicate copy of this paper is enclosed.

Dated: May 17, 2006

Respectfully submitted,

By 

Katherine L. Neville

Registration No.: 53,379

MARSHALL, GERSTEIN & BORUN LLP

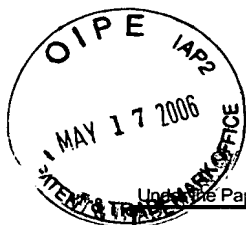
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Agent for Applicant



PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/823,906-Conf. #6103	
	Filing Date	April 14, 2004	
	First Named Inventor	David E. Clarke	
	Art Unit	1614	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	4	Attorney Docket Number	30754/39959

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MARSHALL, GERSTEIN & BORUN LLP		
Signature			
Printed name	Katherine L. Neville		
Date	5-17-06	Reg. No.	53,379

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MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Dated: 5-17-06 Signature: (Juan Quintero)

Form PTO-1449 (Modified)

Atty. Docket No.

30754/39959

Serial No.

10/823,906

INFORMATION DISCLOSURE STATEMENT

Applicant(s)

David E. Clarke

Filing Date

April 14, 2004

Art Unit

1614

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Issue or Publication Date	Name	Class	Subclass	Filing Date (If Appropriate)
A1	3,598,122	8/10/1971	Zaffaroni	204	607	
A2	4,788,189	11/29/1988	Glazer	514	221	
A3	4,965,074	10/23/1990	Leeson	424	449	
A4	4,971,079	11/20/1990	Talapin	131	159	
A5	5,016,652	5/21/1991	Rose et al.	131	270	
A6	5,227,391	7/13/1993	Caldwell	514	343	
A7	5,272,155	12/21/1993	Arneric et al.	514	315	
A8	5,342,623	8/30/1994	Enscore et al.	424	448	
A9	5,635,203	6/30/1997	Gale et al.	424	448	
A10	5,780,051	7/14/1998	Eswara et al.	424	449	
A11	5,977,131	11/02/1999	Nagel	514	300	
A12	6,004,970	12/21/1999	O'Malley et al.	514	282	
A13	6,280,761	8/28/2001	Santus	424	435	
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A19	6,620,428	9/16/2003	Hoeck et al.	424	449	
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A22	6,699,497	3/02/2004	van Osdol et al.	424	448	

EXAMINER:

DATE CONSIDERED:

Form PTO-1449 (Modified) INFORMATION DISCLOSURE STATEMENT	Atty. Docket No. 30754/39959	Serial No. 10/823,906
	Applicant(s) David E. Clarke	
	Filing Date April 14, 2004	Art Unit 1614

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Publication Date	Country	Translation	
				Yes	No

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C1	ALLGAYER, Hubert, <i>Gastrointestinal Pharmacology</i> , Sulfasalazine and 5-ASA Compounds, 21:643-658, 1992.
C2	FREE et al., <i>Brain Research</i> , Surface and Intracellular Nicotinic Receptors Expressed in Intact Adrenal Chromaffin Cells: Direct Measurements Using [3H]epibatidine; 974:60-9, 2003.
C3	GUSLANDI, M., <i>International Journal of Colorectal Disease</i> , Long-Term Effects of a Single Course of nicotine Treatment in Acute Ulcerative Colitis: Remission Maintenance in a 12-Month Follow-Up Study, 14:361-262, 1999.
C4	IOANNIDES et al., <i>New England Journal of Medicine</i> , Rectal Administration of Metronidazole Provides Therapeutic Plasma Levels in Postoperative Patients, 305:1569-70, 1981.
C5	Japanese Pharmacology & Therapeutics, 22:93-121 (1994).
C6	KAWASHIMA et al., <i>Life Sciences</i> , The Lymphocytic Cholinergic System and its Biological Functions, 72:2101-9, 2003.
C7	LASHNER et al., <i>Digestive Diseases and Sciences</i> , Testing Nicotine Gum for Ulcerative Colitis Patients, 35:827-32, 1990.
C7	LI et al., <i>Current Gastroenterology. Reports</i> , Assessing Disease Activity and Disease Activity Indices for Inflammatory Bowel Disease, 4:490-96, 2002.
C9	LICHTIGER et al., <i>New England Journal of Medicine</i> , Cyclosporine in Sever Ulcerative Colitis Refractory to Steroid Therapy, 330:1841-1845, 1994.
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C11	RACHMILEWITZ, D., <i>British Medical Journal</i> , Coated Mesalazine (5-aminosalicylic acid) Versus Sulphasalazine in the Treatment of Active Ulcerative Colitis: A Randomised Trial, 298:82-82, 1989.
C12	ROBINSON et al., <i>Journal of Laboratory and Clinical Medicine</i> , Regulation of Neutrophils in Ulcerative Colitis by Colonic Factors: A Possible Mechanism of Neutrophil Activation and Tissue Damage, 130:590-602, 1997.
C13	SANDBORN, W., <i>American Journal of Gastroenterology</i> , Nicotine Therapy for Ulcerative colitis: A Review of Rationale, Mechanisms, Pharmacology and Clinical Results, 94:1161-1171, 1999.

EXAMINER:	DATE CONSIDERED:
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Form PTO-1449 (Modified) INFORMATION DISCLOSURE STATEMENT	Atty. Docket No. 30754/39959	Serial No. 10/823,906
	Applicant(s) David E. Clarke	
	Filing Date April 14, 2004	Art Unit 1614

C14	SINGH, PARMINDER et al., "Iontophoresis in Drug Delivery: Basic Principles and Applications", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 11:161-213, 1994.
C15	Sogo Rinsho (Comprehensive Clinic), 43:1725-1729 (1994).
C16	TAMBOLI et al., <i>Best Practice and Research Clinical Gastroenterology</i> , Probiotics in Inflammatory Bowel Disease: A Critical Review, 17:805-20, 2003.
C17	TANG et al., <i>Cellular Signalling</i> , CaM Kinase II-Dependent Phosphorylation of Myogenin Contributes to Activity-Dependent Suppression of nAChR Gene Expression in Developing Rat Myotubes, 16:551-63, 2004.
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C19	The Merck Manual, Seventeenth Edition, p. 309, 1999.
C20	WICK, Steven, "Developing a Drug-In-Adhesive Design for Transdermal Drug Delivery", <i>Adhesives Age</i> , 38(10):18-24, 1995.

EXAMINER:	DATE CONSIDERED:
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